

accepted. These application fees are not refundable.

[52 FR 20599, June 2, 1987, as amended at 53 FR 4963, Feb. 19, 1988]

§ 1301.13 Persons exempt from fee.

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps, Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's officer certifies to the status and address of the registrant.

(c) Exemption from payment of a registration or reregistration application fee does not relieve the registrant of any other requirements or duties prescribed by law.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971; 36 FR 18728, Sept. 21, 1971; 38 FR 756, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 53 FR 4963, Feb. 19, 1988; 59 FR 8859, Feb. 24, 1994]

REQUIREMENTS FOR REGISTRATION

§ 1301.21 Persons required to register.

Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or pursuant to §§ 1301.24–1301.29. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 13386, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1301.22 Separate registration for independent activities.

(a) The following groups of activities are deemed to be independent of each other:

(1) Manufacturing controlled substances;

(2) Distributing controlled substances;

(3) Dispensing controlled substances listed in Schedules II through V;

(4) Conducting research with controlled substances listed in Schedules II through V;

(5) Conducting instructional activities with controlled substances listed in schedules II through V;

(6) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V, however, pursuant to § 1301.24, employees, agents, or affiliated practitioners, in programs, need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to § 1305.03;

(7) Conducting research and instructional activities with controlled substances listed in Schedule I;

(8) Conducting chemical analysis with controlled substances listed in any schedule;

(9) Importing controlled substances;

(10) Exporting controlled substances; and

(11) A compounder as defined by § 1301.02(d).

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:

(1) A person registered to manufacture or import any controlled

substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture or import;

(2) A person registered to manufacture any controlled substance listed in Schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I shall be authorized to manufacture or import such class if and to the extent that such manufacture or importation is set forth in the research protocol described in § 1301.33 and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;

(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to § 1301.26, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to import such substances for research purposes, to distribute such sub-

stances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.26, and to conduct instructional activities with controlled substances;

(6) A person registered to dispense controlled substances in Schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances, except that a mid-level practitioner, as defined in § 1304.02(f), may conduct research coincident to his/her practitioner registration only to the extent expressly authorized by state statute.

(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substance listed in Schedule I for which he has filed and had approved a research protocol.

[36 FR 7778, Apr. 24, 1971, as amended at 36 FR 18728, Sept. 21, 1971; 37 FR 15918, Aug. 8, 1972; 38 FR 756, Jan. 4, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973; 58 FR 31175, June 1, 1993]

EDITORIAL NOTE: For FR citations affecting § 1301.22, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 1301.23 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by